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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/463,474

Applicant(s)

SINN ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,13,15,16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,13,15,16 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Pursuant to the directives of paper No. 19 (filed 7/3/02) claims 1, 4, 5, 7-10, 13, 15, 16 have been amended, and claim 18 added. Claims 1, 2, 4-10, 13, 15, 16, 18 remain pending. Applicants' arguments filed 7/3/02 have been considered and found persuasive in part.

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The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 recites that the serum albumin "comprises" a human serum albumin. Certainly, one could begin with naturally occurring human serum albumin and add amino acids to either end, or to any of the side chains. But if this is done, is the new protein thus obtained really a "serum" albumin? Applicants are requested to point to the page and line number where support for the phrase at issue can be found.

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Claims 1, 2, 4-10, 13, 15, 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have asserted that the claimed compounds can be used to "distinguish cancerous or inflamed tissue from healthy tissue". However, there is no evidence of any such preferential accumulation. Nor is there any reason to believe that there would be such. Applicants have argued that a declaration will be provided at some point in the future. As such, it is appropriate to maintain this ground of rejection until the declaration is submitted.

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Claims 1, 2, 4-10, 13, 15, 16 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 recites the terms "acidic amide bond", and "acidic ester". These are not terms which are known as such. It would be helpful if applicants would provide an example of a compound which contains an amide bond but which does not contain an "acidic amide bond", and similarly, example of a compound which contains an "acidic ester" but which does not contain an (non-acidic) ester moiety. If applicants would be willing to do this, it would help to advance the prosecution. Alternatively, if the terms "amide" and "ester" are intended, these are certainly recognized terms.

- Claim 1 line 3 recites the term "joined". However, this is an inexact term. If there is a covalent bond, it is suggested that the term "joined" be deleted, and replaced with the phrase *bonded to one another*.
- Claim 8 recites the term "acridic acid". In the entire Chem Abstracts database, there is not a single reference to this term. There are, however, two references to the term "Acridic A 405". Accordingly, the term "acridic acid" is not well known in the art. In response, applicants have pointed out that the term "acridic acid" can be found in an English/German dictionary, and that the translation of the term "acridic acid" is "acridinsäure". However, a translation of the term at issue from English **into German** does not in any way help make its meaning clear to persons who are familiar only with the English language. Terms used in claims in U.S. Patent applications must be clear to persons who are familiar with English only. Use of the phrase "acid of acridine" would constitute a step in the direction of overcoming this ground of rejection. Certainly, the examiner will stipulate that chemists in the U.S. are familiar with the term "acid" and with the term "acridine". However, if applicants were to use the phrase "acid of acridine", it would raise another question. The term "acid of acridine" could refer to an acid salt of acridine, or it could refer to a compound in which a carboxyl group (or other acidic group) is bonded to acridine, such as acridine-9-carboxylic acid. (See page 3, original spec, 9th line from last). What is intended here?
- Claims 4 contains an inherent contradiction. On the one hand, line 2 of the claim mandates that the conjugate comprise "a carrier", i.e., **one** carrier, but on the other hand, the last two lines of the claim mandate that multiple carriers are present. Thus, the question arises, which controls, the requirement that there be one carrier, or the requirement that there be a multitude of carriers? The same issue applies in the case of claim 9.
- Claim 10 is indefinite as to the process steps. First, claim 10 makes reference to the term "moiety". While this is appropriate in the case of claim 1, it does not make sense chemically when describing reactants. One cannot have a vial which contains just a "moiety", and one cannot react just a "moiety" with a compound. One reacts one compound with another. Second, how does one achieve covalent bonding? Does covalent bonding occur spontaneously when a fluorescent compound is combined with a protein, or are there steps that a chemist must take? It is not enough to say merely that the chemist is free to make his own determination as to how

to proceed. Third, the claim is rendered indefinite by its failure to recite a step for isolating the final product. The following is an example of a format that could be used; however, no determination has been made as to what would or would not constitute new matter:

A method of preparing a conjugate according to claim 1 comprising

(a) reacting a carboxyl-bearing fluorescent compound with a protein in the presence of a coupling agent for a time and under conditions effective to form the conjugate according to claim 1, and

(b) isolating the conjugate of step (a).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



DAVID LUKTON
PATENT EXAMINER
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